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GENERIC PRESCRIPTIONS AND DISPENSING IN INDIA- PROBLEMS AND SOLUTIONS - A STUDY

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ABSTRACT

Brand name prescriptions are widely practiced by Indian doctors. One generic drug may have hundreds of branded products and all brands are prescribed by some doctors. Branded medicines are always costlier compared to generic products.. Studies have shown that compared to generic items, branded medicines are 30 to 200 per cent or more costly in India. The Prime Minister of India Mr Narendra Modi in April 2017 announced that the Government of India intend to ensure that doctors prescribe medicines by generic name only. Apart from price, brand name prescriptions promote irrational prescriptions as in the case of Fixed Dose Combinations. There are also instances of branded products containing same or similar active ingredients are prescribed to patients. Sometimes different generic medicines are marketed under same brand names by different manufacturers. If the drugs control departments in the country are modernised, empowered and utilise the scientific advantages including information technology, the menace of spurious and low quality medicines reaching the market can be avoided. Computerised tracking system and prescription auditing will help to make the pharmacy practice more professional and ethical. Bar coding should be made mandatory for all medicines manufactured/ marketed in the country. The firms marketing not of standard quality medicines should be severely punished. All medicines irrespective of whether they are having generic or brand names shall be of standard quality and the enforcing authorities should ensure the quality of medicines.

KEYWORDS: Generic medicines, generic prescriptions, generic dispensing, branded medicines, Indian generics.

INTRODUCTION

While inaugurating a multi-speciality charitable hospital in Surat in Gujarat, on 17th April 2017, Prime Minister of India Narendra Modi announced that the government of India intend to ensure that doctors prescribe medicines by generic name only as they are cheaper than respective branded medicines. The Prime Minister also said that the doctors write prescriptions in such a way that the poor people do not understand their handwriting and they end up buying costly medicines from the private stores, while quality generics are available at lower costs. 'We will bring in a legal framework by which if a doctor writes a prescription, he has to write generic names in a legible manner.' the Prime Minister said.

The very next day, on April 18, Ministry of Health and Family Welfare, Government of India wrote to the Addl. Chief Secretaries/ Principal Secretaries of Health and Family Welfare of all States and Union Territories mentioning "Please find enclosed a coy of Notification No MCI-211 (2)/2016 (Ethics)/131118 issued by Medical Council of India which has come into effect on 8th October, 2016. The provision mandates that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs"[1]. All the state governments and union territories initiated steps to implement the same in their regions immediately on receiving the communication.

On 21st April, 2017, Medical Council of India (MCI) directed the medical community in India represented by the Deans, Principals of Medical Colleges, Directors of hospitals and Presidents of State Medical Councils, to follow its 2016 notification in which the MCI had amended the clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 mandating the doctors to prescribe medicines by generic names in place of brand names. The apex medical regulator of India has also warned the doctors that if they fail to comply with the guideline or violate clause 1.5 of Ethics Regulation, suitable disciplinary action will be taken by the respective State Medical Council or the MCI [2]. Prime Minister's April 17 declaration and the subsequent actions at the level of the Health Ministries at the central and state levels, the timely strong batting by the MCI, all have opened serious discussions at various levels in the country on different aspects of prescriptions.

Modern Medicines in India

Diseases are as old as human beings and medicines are the essential weapons required to fight against diseases and ailments. In the beginning our forefathers identified medicines from the food items and natural substances including flora and fauna. India has a long tradition of using herbal and natural items as medicines as well documented in Ayurveda and other Indian Systems of Medicine. By the 20thcentury chemical substances became the active ingredients of the medicines. With the discovery of newer medicines, both life expectancy and consumption of medicines increased considerably.

Modern medicines were introduced and popularised in India by the British during the colonial period. Till then indigenous medicines were predominantly used in the country. In return, the people of India gave a beautiful name to modern medicines- "English Medicines". The first modern medicine manufacturing unit in India- Bengal Chemicals and Pharmaceuticals- was started in 1901 in Kolkotta, by Prafulla Chandra Ray. It was after 30 years that the first Pharmacy degree course was started in Banaras Hindu University in 1932 by Prof M L Schroff.[3]

At the time of independence India was producing drugs worth rupees 10 crores per year and the country was having only 5 pharmacy colleges. By 2017 the pharmaceutical industry in India could produce drugs worth rupees one lakh crores. The pharmaceutical market of the country is now the third largest in terms of volume / quantity and the thirteenth largest in terms of value. There are about 20,000 registered pharmaceutical manufacturing units in India which can cater more than 70 per cent of the country's total medicine requirements. About 1300 units are WHO- GMP approved and many of them are US- FDA approved. The organised sector of Indian pharmaceutical industry consists of about 300 firms which account for 70 per cent of the products in the market. Top 10 firms govern about 30 per cent of total products in India. Over 8 lakh licensed retail outlets including both community and hospital pharmacies are working in the country. In January 2005, India introduced the product patent system replacing then existing system of process patent.

The number of pharmacy colleges in the country increased from 5 in 1947 to more than 1200 in 2016. These institutions provide programs like B.Pharm, M.Pharm, PharmD and PhD programs in addition to the two year D.Pharm after plus two level education. With the introduction of the six year doctor of pharmacy (Pharm.D) in 2008, Indian Pharmaceutical education got global acclamation and acceptance.

In spite of all the achievements and wonderful developments in the area of pharmaceutical industry and education systems in the country, the pharmacy practice area including medicine distribution and dispensing system in the country are still in its tradition way. It is often governed by traders and commercial interests. Computerisation and e-governance based prescription filing and medication therapy management (MTM) programs are yet to be implemented in the community and hospital pharmacies. Professional services like medication auditing, pharmacovigilance, drug information, patient counselling, pharmacoeconomics and pharmaceutical care are not yet made integral components of the pharmacy practice. Regulatory requirements of professional supervision and scientific storage are not yet ensured in majority of the practice centres.

Drugs Vs. Medicines

Is there any difference between the terms *drug* and *medicine*? Generally both the terms are used as synonyms. However technically and legally the two terms are different. Indian laws clearly defines the term 'drug' and shows how medicines are related to drugs. However it is silent in the definition of medicine and its relationship to a drug. A drug is the active ingredient with certain pharmacological function. According to the Indian statutory provisions, all medicines are Drugs[4]. A *drug* becomes a *pharmaceutical product* when a manufacturer adopts the active ingredient in dosage forms like tablet, capsule, injection etc. When a pharmacist dispenses the product to a patient, it becomes a *medicine.* Generally speaking, we can define drug as the active substance or ingredient and medicine is its formulated dosage form.

One Medicine, Different Names.

Medicines are today known by different names and each medicine is having at least three names- Chemical name, Generic name and Brand name (Table No1). Rarely medicines are also known by Code number which is an intermediate designation staying with the compound in its initial laboratory investigations for pharmacological activity through the clinical trials (Box No 1). Chemical name of the drug is based on its chemistry or structure and is mainly used in advanced education and research areas. It may not be user friendly to remember or handle by general public.

Table 1: Different names of medicines.

Generic Name	Chemical Name	Brand Name
Paracetamol	Para Aceto Amino Phenol	Fepanil, Calpol, Crocin
Aspirin	Acetyl salicylic acid	Ecosprin, Disprin
Metformin	1-1 dimethyl biguanide	Glucophage
Ampicillin	Aminobenzyl penicillin	Roscillin Unasyn, Sulbacin

Generic name is a shortened, popular and easy to remember name of a drug. It is the international non-proprietary name (INN) and is generally simple, easy to recognise and recall. Generic name is followed by World Health Organisation (WHO) and various countries in the world. Rarely some countries may opt their own generic names for certain drugs and a classical example is Paracetamol which is more known by the name Acetaminophen in USA. Some countries have their own official body for assigning the generic names to the drugs.

Box No 1. Code Number for medicine

It was Paul Ehrlich who introduced the practice of using code numbers. He used code numbers to compounds employed in his search for the 'magic bullet' to cure syphilis. His compound '606' became more popular than the name of the drug Arsphenamine or its first brand 'Salvarson'. The drug was introduced in clinical use in 1910 by Paul Ehrlich and Sahachiro Hata and marketed by Hoechst Pharmaceuticals under the brand name 'Salvarson'. Similarly, the WHO approved abortion pill Mifepristone was introduced under its code number 'RU 486' first in France in 1987 and then in other parts of the world. RU 486 became more popular than its other names.

All text books and reference books in health care and science handle only generic names and the students of medicine, pharmacy, nursing and other health care disciplines study only generic names of medicines at the academic levels. Generic name is the 'official' or 'real' name of a drug and is followed by all government departments, offices and agencies. WHO is always batting for generic prescribing as part of its strategy to ensure rational medical treatment and prescriptions suitable to local needs. Health insurance companies, both private and government, always promote generic drugs and require substituting a generic for a branded prescription. In countries like USA insurance plans also require the patient to pay the entire cost of brand name drug if he/she don't accept the available generic.

Brand name, also known as trade name, is a proprietary, fancy, business name given by the manufacturers to distinguish their products from that of others. Easy to remember and catchy

short names are selected as brand names, and each firm puts efforts in selecting its brand names. It relates entirely to the finished product which may have own flavour, colour and taste with unique packing and labelling style. Newly discovered products in the market economy countries are generally sold by their brand names. Through their high voltage advertisements, marketing and sales promotion strategies, the manufacturers promote and popularise the brand names in such a manner that even the scientific community may often be confused between the generic and brand names. As in the case of Gentamycin (generic) and Garamycin(brand) or Dexamethasone (generic) and Dexona / Dexasone (brand) or Minocycline (generic) and Minocin (brand), it is often difficult to distinguish certain generic and brand names as brand name is a shortened version of generic name. Branded medicines are always costlier compared to generic products. In USA, Canada, and UK generic drugs cost 20- 80 percent less than their brands. Studies conducted by the authors, indicate that the price variation ranges from 30 to 200 per cent or more in India.

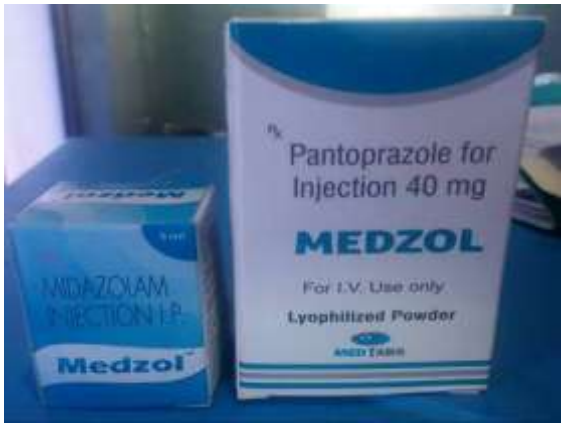

Fig 1: Brand Name Medzol of one firm is Prantoprazole (used for acidity) while other brand contains Midazolam (used for seizures and insomnia).

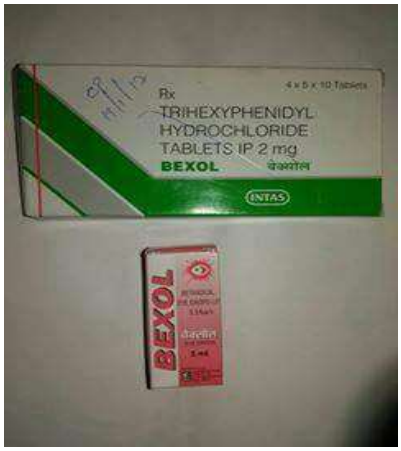

Fig 2: Brand name Bexol of one firm is Trihexyphenidyl (for Parkinson disease) while the other brand is eye drops for infection.

One generic drug may have hundreds of manufacturers and brand names in India. The authors could note 1840 brands of Paracetamol, 1255 brands of Ofloxacin and 1249 brands of Amoxicillin available in Indian pharmaceutical market from the web site of Drugsupdate.com (http://www.drugsupdate.com/brand/showavailablebrands/93/63) accessed in May 2017. Can any Indian Doctor remember so much brand? The practice is simple one prescribes his/her own choice. All brands are prescribed by different prescribers. There are also instances where different generic medicines are given same brand names by different manufacturers causing serious health issues and hazards (See Fig No 1, No 2 and No3)**.** Sometimes the different branded products containing same or similar active ingredients are prescribed to patients resulting in over dosage and consequent toxicity.

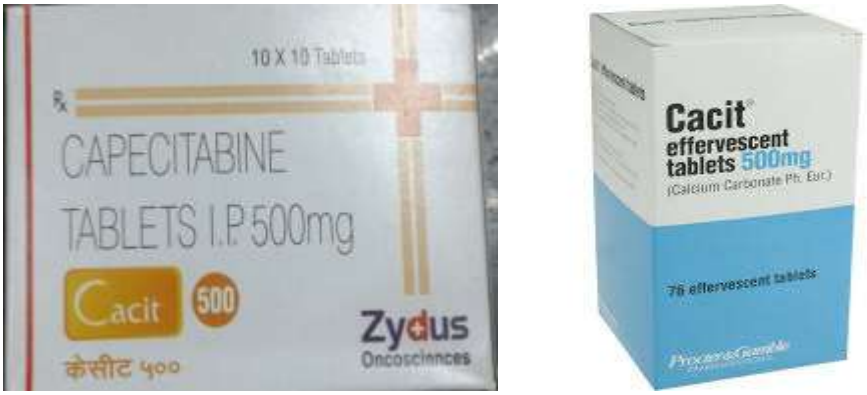

Fig 3: Brand Name Cacit of one firm is Capecitabine (used for colon cancer treatment).while other brand contains Calcium (used for calcium deficiency or as antacid).

What is branded generic?

When a new drug is introduced, it is marketed under a brand name by the original firm and will be a monopoly item till the end of the patency period. Once the patency period is over, other firms can also manufacture and market the drug either in generic (INN) name as such or under their own brand names. Generic medicines are off patent drugs, marketed exclusively with generic or INN names, avoiding brand names. If the generic drug is marketed under a brand name, it becomes and branded generic. A branded generic is a drug that is bio-equivalent to the original product but is marketed under another firm's brand name. A branded generic is a generic molecule promoted through its brand name.

Brand names as promoters of FDCs

Brand names are used for marketing large number of irrational formulations in the market. The organised sector has maintained dominance in the medicine market mainly through their branded products containing multiple ingredients often known as fixed dose combinations (FDCs) and charging exorbitant prices. These FDCs account for 40 - 45 percent of medicines in Indian market. It is to be noted that the Government of India banned 344 FDCs in March 2016 through a gazette notification. Though the banning was scraped by the High Courts by December 2016 for certain technical lapses, their market has decreased considerably and by making generic prescriptions mandatory for the country. Such FDCs will either vanish from the scene or become less popular in due course. It is worth noting that only very few combinations are scientifically proved to be useful in drug therapy and such items are included in the essential medicines list (EML) of WHO or the National Medicines List (NML) of India. Their number is only in the range of 30 to 50.

Patient Counselling and Pharmacoeconomics in pharmacy practice

Till 1950s patients were not made aware of the medicines prescribed to them. Those days, it was argued that such information will help to promote self-medication among the society. The introduction of oral contraceptive pills and its approval by US- FDA in 1960 and the evolvement of the consumer right protection movement initiated by Ralph Nader in America helped to shape changes in the drug marketing concepts in 1960s. It was during that time that the WHO came forward to promote the concept of drug information and patient counselling to ensure drug safety and promotion of rational use of medicines. Later in the 1980s the concept of Pharmacoeconomics dealing with the cost of medicines and their benefit, effectiveness and utility was also introduced in the area of drug therapy and pharmacy practice.

Today the patient, as a consumer of medicines, has every right to know about the medicine, its manufacturer and the cost before being prescribed, dispensed and administered. Promotion of branded medicines necessitated the introduction and promotion of drug information, patient education and pharmacoeconomic counselling services to the patients as a particular drug is manufactured under different brand names with varying prices and packing. Today pharmacists have the responsibility to provide patient counselling both in hospital and community pharmacies as a part of their professional duty. The Pharmacy Practice Regulations 2015 as notified by the Government of India also specify patient counselling a

professional responsibility for practising pharmacists. With the introduction of the six year Doctor of Pharmacy (Pharm.D) in 2008 and the popularisation of pharmacy practice education, the Indian pharmacy practice scenario is fully capable of providing such services and ensure pharmaceutical care to the patients.

Generic prescription - international perspective

Generic name being the scientific or official name, many countries, follow the system of prescription writing and dispensing based on generic name of the medicines. Health Insurance agencies, World Health Organisation, international, national and regional medicine procurement agencies are all follow the generic system.

In 1967, the Sainsbury Committee (Committee of Enquiry into Pharmaceutical Industry) of Great Britain recommended that brand names for all new prescriptions should be banned. But the Labour Government could not implement the suggestion due to the pressure of the industry. In Soviet Russia, exclusive use of generic names started in 1960s itself. In China too generic names are popularly used and the Chinese Food and Drug Administration (CFDA) strictly enforce the regulations.

Legislative measures to promote generic nomenclature started with the Drugs (Generic Names) Act 1972 of Pakistan which banned any drug prescribed, dispensed, sold or distributed under any brand, patent or proprietary name. Later this Act became less effective as in the case of Indian Drugs and Magic Remedies Objectionable Advertisement Act 1956 in its effective implementation.

In USA, generic substitution is regulated not by federal legislation but by state legislation. Today drug product substitution laws exist in all States in the USA. Within certain limitations, the laws allow pharmacists to select and dispense, a less costly, but therapeutically equivalent drug product for the one specifically prescribed by the physician. The State laws often allow patients the option of requesting the brand products at their own expense. The Pharmacist is required to pass on any savings in cost to the patient or the customer.

In Norway only about one thousand substances are on the market and no new drugs are introduced unless they are judged to be effective and better than the existing items. Norway requires the generic names to be included in the drugs advertisements aimed at the general

public. As a part of their National Drug Policy, Nigeria is insisting on generic prescribing since 1991.

Indian Situation

In the 1975 the Hathi Committee strongly advocated for the abolition of brand names of medicines in India.[7] The prescription documenting and registering system in the country is still in the process of establishment. The community pharmacies were under the control of the traders and non- professionals until 2000 AD. Most of the pharmacists in community pharmacies and a good percentage in hospital pharmacies were less qualified and lacking professionalism. It was mainly due to the fact that the nation permitted pharmacy council registration to a section of people who were not educationally and professionally qualified. Under the banner of "qualified person" people not having a degree or diploma qualification in pharmacy were permitted to register with the Pharmacy Council and practice pharmacy. It is true that those days there were only very few Pharmacy Colleges in the country and diploma and degree pharmacists were in short.

In 1972 sub Rule 11 A was incorporated to Rule 65 of the Drugs and Cosmetic Act Rules 1945. This Rule 65 (11A) is an anti-substitution Rule and says " No person dispensing a prescription containing substances specified in (Sch. H or X) may supply any other preparation, whether containing the same substance or not in lieu thereof". This was incorporated at t time when the community pharmacies (medical stores) were in the total control of traders and most of the available pharmacists were 'qualified persons'.

The Rule 65 (11A) was incorporated primarily to control the unethical trade practices prevalent at that time among the private medical stores in India. Moreover the anti-substitution Rule was not seriously taken up by the pharmacy profession, its members or their organisations. The main reason was the incapability of the enforcing agencies to implement the Rule in the absence of a prescription registering and filing system in the country.

Now with the notification for generic prescription writing, the Rule 65 n (11A) becomes ineffective and infructuous. Abolition of brand names will considerably help in bringing professionalism and promotion of rational drug usage. Doctors who are handling generic names at prescription stage will always be compelled to show more professional approach than those going by trade names. This is also true in the case of Pharmacists dispensing generic medicines.

Studies conducted in various countries have shown that generic prescribing increases continuously with the training given to health care professionals and the medicine information and patient counselling services provided to patients. It was also found that majority of the doctors who are strongly committed to the brand name prescriptions are centred in cities and towns. Negative influencing factors like pressure from the pharmaceutical industry or their agents are minimum at rural areas.

Brands and Quality

Does branding of drugs assure quality? The answer is always 'No'. The quality of a medicine is no way related to its generic or brand names. A newly approved medicine within its patency period is a monopoly product at the global level and is marketed under brand name. Being an original research product its quality is ensured as of accepted levels of standards. For such monopoly items it is true that the brand name can help to ensure a quality product. When a new drug is discovered, its quality parameters and quality control methods and procedures are also well described and prescribed. Later when other manufacturers enter into the scene, they are bound to follow the established / existing or its improved methods for quality tests. Even after the patency period, such brands of original firms often get the name as 'brand leader' among the branded generics.

Maintenance of quality is the responsibility of the manufacturer which is to be ensured and governed by the regulatory agency- Drugs Control department or FDA. The quality of medicines depends mainly on the integrity, capability and mentality of the manufacturer to follow the laws, regulations and guidelines. Medicines have only one standardised quality as specified in the respective Pharmacopoeias or other official books and publications. The Drug Rules and Laws clearly specify the quality assurance parameters starting from the good manufacturing practice and good laboratory practice to the good storage and dispensing aspects. Every manufacturer is duty bound to ensure the quality of each batch of medicines before being shifted from the production unit to the marketing or distribution system.

Spurious medicines (fake items) and substandard medicines (genuine items that fail to meet standards of quality, purity, strength and packing) are some of the serious drug related problems in the country. Studies have shown time and again that branded medicines are in no way assurance of quality. A recent two year study conducted by the National Institute of Biologicals for the Central Drugs Standard Control Organisation (CDSCO) of India found that 0.02 per cent of the marketed medicines were spurious and 3.16 per cent substandard. It

also showed that 3 per cent of the medicines were substandard at the community pharmacy (retail outlets) levels. At the level of government hospitals (hospital pharmacies) the figure was a staggering 10 per cent. It was also found that big pharmaceutical firms like Pfizer, Cipla, Dr Reddys, Zydus etc have produced and marketed substandard branded products. The generic major firm from Gujrat Mercury Laboratories too produced generic substandard medicines.[5]

Studies on the number of substandard, misbranded and spurious medicines reported by the various state drugs control departments and the drug testing laboratories of the Government of India reveal that substandard items are almost equally distributed among branded and generics and the instances of spurious are more among branded items. In the case of medicines marketed under generic names, the issue of misbranded and spurious are very rare.[6]

Role of licensing authority in quality assurance

The licensing authority, namely the drugs control or FDA departments, have a key role to play in ensuring the quality of medicines manufactured and / marketed in the country. There are about 1600 drug inspectors and officers for the central and state drug control departments and their regional offices in India. The process of modernisation and updating the system of drugs control are not satisfactory. Being the watch dog of quality control and assurance of medicines, it is high time that the entire system of drug control is made smart enough with supporting facilities and competence. The departments have to maintain a computerised registry for all licensed Pharmaceutical units / importers and their products. It will help the authorities for tracking the items of various manufacturers.

Every manufacturer or importer of medicine shall be directed to upload the test reports of each batch of medicine before being marketed. The present system of sampling and testing of medicines needs to be revamped. Taking random samples and getting them tested after two years period is of no use, and is only a formality to comply with duties. If the system of e-portal registration right from the manufacturer/ importer level to the dispensing levels at hospitals and community pharmacies is introduced in the country that will help to solve many of the existing issues and problems adversely affecting the practice of pharmacy. Such a system will help to ensure prescription registry for the country and thereby prevent the dispensing of schedule medicines without valid prescriptions. Prescription monitoring and auditing will also become feasible and help to ensure drug safety. It will also help to prevent

many existing unethical practices including unfair trade practices and marketing substandard and spurious items of medicine.

How to ensure quality of generic medicines?

An analytical study of the existing problems and situations in the country leads to the conclusion that the following are some of the special steps required to ensure quality of medicines in addition to the hitherto followed and existing measures.

Empowering manufacturers and regulators

Brand name prescriptions force the patients to purchase a particular product of a particular firm, while hundreds of firms may be manufacturing the item. It is not possible for a prescribing physician or a dispensing pharmacist to ensure the quality of a branded medicine without the support of a testing laboratory. According to the provisions of Indian Drugs and Cosmetics Act and Rules, it is the responsibility and bounded duty of the manufacturer to ensure the quality of medicines, generic or branded, manufactured by them. Manufacturers have to test each and every batch of medicine produced for compliance with Pharmacopoeial standards and specifications. The tests can be conducted either in their own laboratories or in an approved laboratory. They have to maintain a separate register for such tests. Only after ensuring the quality and documenting the related test reports, a manufacturer can release a particular batch of medicine for marketing or use.

It is the responsibility of the law enforcing authority (FDA/ Drugs Control Department) to supervise, govern and ensure that the manufacturers do comply with the quality assurance and other legal requirements as per the statutory provisions. This is done in different countries in their own ways. The Drugs Control department shall function as the watch dog in ensuring the quality of medicines manufactured and marketed in the country.

It is true that the existing 1600 officers of the department are not sufficient enough to manage the existing pharmaceutical sectors in the country. What is more important is to make the existing and available system efficient and effective utilising modern concepts and innovations. The drug sampling and testing methods currently followed in India are pretty old and outdated. The system warrants necessary modifications and effective scientific approaches. If the manufacturers are directed to upload the test reports of each batch of their medicines in the websites / e-portals before being released for sales or use, that will help to

ensure quality more. Severe punishments should be given to those responsible for marketing spurious and not of standard quality medicines.

Offices of the drug inspectors should be modernised and each inspector / officer shall be a drug researcher. The drugs control department of each state shall also function as a centre for training and research on matters related to drugs including policies and regulations. The qualification for the drug inspectors and higher officers shall also be necessarily re-prescribed with this perspective. The officers shall be encouraged for higher specialised qualifications including doctoral/ PhD programs.

Permission for the manufacture of a formulation containing single ingredient shall be given with generic name only. Only in the case of new and permitted multiple ingredient products (FDC) brand names may be permitted. Pharmacoeconomic evaluation reports have to be insisted for all types of licenses from the Drugs Control department from manufacture to marketing. The services of registered pharmacist shall be ensured in the community and hospital pharmacies throughout the working time as necessitated by the statutory provisions. The working pharmacists shall have compulsory dress codes and identity cards.

Barcodes on medicine labels and effective tracking system for regulators

The huge size of Indian pharmaceutical market makes it often difficult for the regulators and monitoring agencies to track medicines, mainly in rural areas and distant villages in various Indian states. This leads to a dangerous situation of marketing low quality and fake medicines being sold in the market.

Barcode is an optical and machine readable form of data used to identify objects. Commonly used bar codes are one- dimensional (1D) or two dimensional (2D) types. In 1D series of black bars and white spaces of varying width are printed on labels, while in 2 D squares or rectangles with dots are printed on labels to uniquely identify the items. Barcode labels are read with optical scanners known are barcode readers or with application soft wares and smart phones with cameras. Scanners measure reflected light and interpret the code into numbers and letters.

Barcodes are used in many retail items in the market. Though the Indian Pharmaceutical industry is very much developed, bar coding is yet to be popularised in pharmaceutical products marketed in the country. It is high time that the barcode shall be made compulsory

for all medicines marketed in the country even if it slightly affects the price structure. Introduction and popularisation of compulsory barcode in pharmaceutical products will help to track and trace the products of individual firms and will also help to ensure that patients get genuine medicines. It will also function as an effective tool to counter the menace of fake, misbranded and spurious medicines reaching the market. Under the barcode system, the primary, secondary and tertiary packs of medicines of each manufacturer will carry the unique barcode allotted by the Drugs Control department.

It is interesting to note that in the background of complaints of spurious medicines from India reaching in international markets, the Indian Commerce Ministry in 2012 made it mandatory for pharmaceutical exporters to have barcode and track and trace system for tertiary and secondary packages of medicines exported from the county. In 2015 the Health Ministry also has initiated the development of a mechanism for tracking medicines for their safety and authenticity in the Indian market. The Government is still working to create an integrated data base with all details of product including batch number, date of manufacture, expiry details, retail price etc which will enable the authorities to track and monitor the medicines manufactured and marketed in India.[8]

Orange Book model publication for Indian firms

Since 1980 the US- FDA is publishing Orange Book regularly. It is a publication of approved drug products with therapeutic equivalence evaluations. This book helps to identify drug products approved on the basis of safety and effectiveness. Publication of a drug product in the orange book is a warranty that it is equal to similar items of other firms listed in the book. India too needs a similar publication listing pharmaceutical products ensuring therapeutic equivalence for approved generic items licensed / approved by the Drugs Control / FDA of India.

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